UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,132	10/01/2003	Fred J. Stutzenberger	CXU-382	3896

22827 7590 09/03/2009
DORITY & MANNING, P.A.
POST OFFICE BOX 1449
GREENVILLE, SC 29602-1449

EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/677,132	**Applicant(s)** STUTZENBERGER ET AL.
	Examiner MAURY AUDET	**Art Unit** 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/30/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *2/6/09*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges applicant's filing of the 1.131 Affidavit swearing behind the primary reference of record (Franzen); however, Applicant has also broadened the claims as originally presented - which was not search at the time of 1st action. Thus, even though new art of record has been cited, the present action is sent Final, as Necessitated by Amendment, broadening (changing) the claimed invention and scope of the search & application of the art found therein- which trumps the 1.131 Affidavit (where normally any new art of record would have to be sent via a 2nd Non-Final Office Action, since it was capable of retrieval on search based on the claims by original presentation; which is no longer the case).

Election/Restrictions

As noted previously:

Applicant's **election without traverse** of Group III, new claims 46-69, as drawn to the **elected invention (NOT species**; see below) in the reply filed on 4/23/08 is acknowledged:

> the following nanoparticle comprising a hydrophobic polymeric core, a hydrophilic linking agent bound to said core, and a biofunctional material comprising a binding site that can bind adhesins on the surface of an enteropathogenic microorganism:

1. hydrophobic polymeric *core* - **polystyrene** (see, e.g., ¶[008], p. 2 of the captioned application);

2. hydrophilic polymeric *linking agent* - **polyethylene glycol** (see, e.g., ¶[009], p. 2 of the captioned application);

3. *biofunctional material* including a binding site that can bind adhesins on the surface of an enteropathogenic microorganism - **a mono- or polysaccharide** (see, e.g., ¶[010], p. 3 of the captioned application).

> The pending claims are directed to a method for agglomerating biologically active microorganisms comprising contacting a first enteropathogenic microorganism with a first nanoparticle, one example of which is identified above as required by the

> Examiner; binding a first adhesin of the first enteropathogenic microorganism to the first binding site of the biofunctional material to form a nanoparticle/microorganism complex; and binding a second adhesin of a second enteropathogenic microorganism to a second binding site of the biofunctional material of the nanoparticle/microorganism complex. All of the pending claims are generic to the above-identified composite

As noted in the Interview Summary (10/29/07 mailing) as to the elected invention:

Applicant telephoned to discuss the outstanding restriction requirement generally and *to clarify that the election of a fully defined structure (or at least substantial core as to the relevant structure therein (biofunctional material) as to the composition* ***is an election of the invention as to the elected Group*****, rather than a species election. Applicant's interpretation is correct**."

Claim Objections

Claims 46-75 are objected to because of the following informalities:

the claims have not been amended commensurate in scope with the elected invention (see above under election); the claimed invention has only been searched in so far as it reads upon the elected invention.

Per the amendment to expressly claim the above, please also expressly claim how each of the 3 are conjugated (by position), which will allow one of ordinary skill in the art to be able to ascertain how to arrive at the new size limitation (average diameter).

Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

> pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to consider when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any experimentation is "undue". These factors include, but are not limited to:

1. The breadth of the claims.
2. The nature of the invention
3. The state of the prior art;
4. The level of one of ordinary skill
5. The level of predictability in the art;
6. The amount of direction provided by the inventor;
7. The presence or absence of working examples;
8. The quantity of experimentation necessary needed to make or use the invention based on the disclosure;

(See: In re Wands USPQ2d 1400 (CAFC 1988)

1. & 2. The breadth of the claims and the nature of the invention:

As amended, the presently claimed invention is now directed to a size limitation above nanoparticle size, and now up to a particle size generally of between about 30 nanometers and about 5 micrometers, as relevant to the binding capacity of the particle to pathogenic microorganisms. Namely, a process for agglomerating any pathogenic microorganism, using a "particle" specifically comprising:

1. hydrophobic polymeric *core* - **polystyrene** (see, e.g., ¶[008], p. 2 of the captioned application);

2. hydrophilic polymeric *linking agent* - **polyethylene glycol** (see, e.g., ¶[009], p. 2 of the captioned application);

3. *biofunctional material* including a binding site that can bind adhesins on the surface of an enteropathogenic microorganism - **a mono- or polysaccharide** (see, e.g., ¶[010], p. 3 of the captioned application).

The breadth of the claimed particle, specifically as to any mono or polysaccharide (surrounding the particles inner core of polystyrene attach to PEG) being able to "contact" and bind the adhesin of any pathogenic microorganism is at issue.

3. The state of the prior art

Carson et al. (US 5416075) teach in col. 1-2 that:

> **Lipoteichoic acid is the adhesin which Streptococcus pyogenes uses to attach itself to oral mucosal cells and this acid is also involved in the attachment of various streptococcal species to human stratum corneum cells.** Lipoteichoic acid also interacts with the host cell receptors, one of which is fibronectin. Fibronectin carries two separate binding sites, one for streptococci and one for staphylococcii. **Glucose and mannose washes have been used to remove coryneform and streptococcal species from the skin.** Common skin microbes such as coryneform species involved in malodor generation and opportunistic pathogenic streptococcal species carry structures that recognize carbohydrates as well as fibronectin. Epithelial cells have "adhesin" recognition structures which interact with fatty acid side chains of lipoteichoic acid.

Carson et al. teach that mono/polysaccharides can 'wash' the entire microorganism off of the body, but there is no indication that glucose/mannose 'bind' or 'agglomerate' ANY 'adhesin' or even specifically lipoteichoic acid of S. pyrogenes.

4./5. The level of one of ordinary skill & the level of predictability in the art

The skill in the art is deemed to be that of the Master's Level chemist in carbohydrate and peptide chemistries, capable of determining what mono/polysaccharides are capable of binding/agglomerating what specific or general adhesins on any pathogenic microorganisms. The predictability is not deemed intrinsic, and only verifiable by testing.

6./7./8. The amount of direction provided by the inventor & the presence or absence of working examples & the quantity of experimentation necessary needed to make or use the invention based on the disclosure

D-Mannose seems to have been the only particle surface-derivatized mono/polysaccharide tested in the Examples.

Example 5 is to an "adhesin-specific nanoparticle" (e.g. not capable of binding just any adhesin of any pathogenic microorganism).

Example 6 of the specification provides testing of a mannose disaccharide as capable of binding heavily to the C. jejuni adhesin, but not necessarily a strong binding capacity to any of the adhesins: *Escherichia coli, Salmonella typhi, Enterobacter aerogenes and Streptococcus faecalis*. Applicant has a number of examples, but the data does not appear sufficient with respect to any number of the other mono/polysaccharides OR pathogenic adhesins as to the correlation to binding/agglomeration. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of a claim will possess the alleged utility. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

CONCLUSION

The breadth of the claims are simply too broad for the reach of the amended claimed invention that somehow a specific size ratio of a nano/microparticle, bearing any surface derivatized mono/polysaccharide, will be able to attach to any adhesion of any pathogenic microorganism - which the disclosures test data can presently support. There is no guidance as to which of the vast array of mono/polysaccharides on the particles surface would be operable for agglomerating the adhesins specific to any pathogenic microorganism. To summarize, reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view to the quantity of experimentation necessary, the noncorrelatable data on mono/polysaccharide surfaced particles to any pathogenic microorganism, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, in view of this unpredictability, the skilled artisan would not reasonable expect any adhesin of any pathogenic microorganism to be bound for agglomeration by any mono/polysaccharide resting on the surface of the polystyrene/PEG particle, absent evidence to the contrary.

Claim Observation

Applicant may wish to consider amending the claims to expressly claim:

1) those specific mono/polysaccharides (e.g. D-mannose) derivatized on the surface of the conjugated polystyrene-PEG particles; AND

2) the specific pathogenic microorganisms found to bind via their specific adhesins.

Conclusion

Applicant's amendment (broadening the particle of the invention from a nanoparticle (e.g. nanometers) to simply a particle, up to about 5 micrometers) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA 5/26/09

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654